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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,216	08/11/2000	Scott J Hultgren	WSHU2005.1	7884

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SENNIGER POWERS LEAVITT AND ROEDEL
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16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/637,216	Applicant(s) HULTGREN ET AL.	
	Examiner Ardin Marschel	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,8,9,13,14,16,17,19,& 136-158 is/are pending in the application.
- 4a) Of the above claim(s) 140-158 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 136 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8,9,13,14,16,17 and 19 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,5,8,9,13,14,16,17, & 19 is/are objected to.
- 8) ☒ Claim(s) 1,2,4,5,8,9,13,14,16,17,19 and 136-158 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 2/2/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

ELECTION BY ORIGINAL PRESENTATION

Newly submitted claims 140-158 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

A complex as now set forth in claims 140-158 is unrelated in structure and function compared to the inhibitory compounds as originally claimed. Such a complex is not expected to have inhibitory activity as the previously claimed compounds due to complexation forming a vastly different structure which no longer has a binding site appropriate for inhibition as claimed. It would be an undue search burden to now search for the complex structure which also lacks the inhibitory function of the compounds as previously claimed due to the vastly different structural features of the invention of claims 140-158.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 140-158 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

NEW MATTER

Claims 1, 2, 4, 5, 8, 9, 13, 14, 16, 17, 19, and 137-139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to include the specific limitation of Z_2 and Z_3 optionally consisting of both peptide and peptide analog residues which has not been pointed to by applicants for support nor found as filed. This limitation is also specifically present now in claim 16. This rejection is necessitated by amendment and is applied to claims dependent from claim 1 due to their direct or indirect dependence.

Applicants pointed to support for newly submitted claims 137 and 138 in the specification on page 6, lines 24-26. Said lines lack, however, the amino terminal motif limitations of said newly added claims. Consideration of page 6 of the specification reveals at lines 18-26 that another limitation is set forth regarding such a compound. This limitation is that the compound contains two alternating hydrophobic residues. Also, said section of the specification lacks the mimic of a chaperone G1 beta-strand as now in claims 137 and 138. These claims thus contain NEW MATTER. This rejection is necessitated by amendment.

Claim 139 is also described by applicants as being supported in the specification at page 6, lines 24-26. Consideration of said support, however, fails to reveal the competitive binding to a pilus subunit hydrophobic groove as now set forth in claim 139. This claim thus contains NEW MATTER. This rejection is necessitated by amendment.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 8, 9, 16, 19, and 137-139 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Flemmer et al. [Bioorganic & Medicinal Chemistry Letters 5(9), pp. 927-932 (1995)].

This rejection is maintained and reiterated from the previous office action, mailed 9/2/03, and applied to newly added claims as necessitated by amendment. Applicants argue that binding characteristics do not meet the claim limitations. In response the claims set forth structural limitations that apparently are meant to define the structural features of a compound as claimed. Since the compound in Flemmer et al. meets the structural features of the instantly claimed compounds, it is deemed to carry with it any binding characteristics as also present in instantly claimed compounds. Regarding specific arguments, the structural features of the compound of the reference clearly corresponds to those in the claimed structures and thus must mimic an "effective" part of a pilus subunit. Applicants then argue that the amino terminus must mimic the

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binding characteristics of the claimed compound but ignore the broader limitation in the instant claims wherein the claimed compound mimics a chaperone G1 strand beta-strand which is not limited to an amino terminal segment. Applicants go on to argue that "binding to" the G1 beta-strand is practiced in Flemmer et al. rather than mimicry as instantly claimed. In response mimicry is deemed to reasonably include "binding to" practice just as a glove mimics the hand that wears it by conforming to its shape. Applicant then argue that the peptide analog interpretation of the Gly(19') to Ser(11') portion of the 19mer of Flemmer et al. is not a peptide analog but do not indicate any specific argument to support this. It is noted that a peptide analog as defined earlier in applicants' arguments is not limited as to length or added moieties over some type of core structure and thus is deemed to be inclusive of the peptide analog defined regarding the 19mer of Flemmer et al. Applicants argument regarding the Thr(7') as being a hydrophilic or hydrophobic amino acid corresponding to X₆ is confusing and thus non-persuasive since said X residue as claimed in claim 1 may be either hydrophobic or hydrophilic.

INFORMALITIES

The disclosure is objected to because of the following informalities:

The symbols utilized for chaperone beta-strand confusingly sometimes contain a subscripted G₁ (See claim 137.) vs. unsubscripted G1 (See claim 138.). Such differences in scientific notation frequently denote actual chemical differences and are thus confusing. This inconsistent subscripting vs. unsubscripting is present in claims 1,

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2, 4, 5, 8, 9, 13, 14, 16, 17, 19, and 137-139 either directly or via dependency from a claim which specifically cites the G1 etc. notation.

Appropriate correction is required.

Claim 136 is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 140-158, drawn to an invention nonelected with traverse, via original presentation. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is

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(571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

April 30, 2004

Ardin H. Marschel 4/30/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER